

Remarks/Arguments

Claim Rejections – 35 USC §102

Claims 1, 2, 5, 6, 8, 10, 11, 22 and 23 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 5,824,638 to Burnside *et al.* Burnside discloses compositions comprising water-in-oil emulsions, whereas the present invention comprises oil-in-water emulsions. Furthermore, the present invention provides compositions in which the emulsifying agent combination of Vitamin E TPGS and linoleic acid does not require the addition of a detergent to emulsify the therapeutic agent. Since many such detergents may be used to lyse cells, for example, it is desirable to provide an emulsifying composition that does not include a detergent. The claims have been amended to provide that the emulsifying composition consists essentially of Vitamin E TPGS and linoleic acid.

In Example 1, Burnside describes the use of Pluronic[®] L44. In Examples 3, 4, 5, 6, 7, 9, 13, 15, 17, 18, and 19, Pluronic[®] (Poloxamer) is used as an added emulsifier. In Examples 8, 10, 11, 12, 17, and 19, Tween[®] is used as an emulsifier.

Claims 1, 2, 5, 6, 7, 8, 10, 11, 22 and 23 have also been rejected under 35 U.S.C. 102(b) as anticipated by WO 99/29300 (Mishra *et al.*). As was disclosed by Burnside, however, Mishra also uses detergent surfactants. For example, Example 1 discloses the use of 200 mg Tween[®] 80 in combination with 130 mg linoleic acid and 108 mg vitamin E TPGS. In Example 2, 375 mg Tween[®] 80 was used, while only 130 mg linoleic acid and 76 mg vitamin E TPGS were included in the composition. Other compositions disclosed by Mishra include Tween[®] 80 and/or Tween[®] 40.

The inventors have discovered that linoleic acid is relatively unique in that it may be used in conjunction with vitamin E TPGS to improve the emulsifying properties of vitamin E TPGS. Other similar lipids tested by the inventors failed to provide this result. Neither Burnside nor Mishra describe compositions such as those provided by the inventors, which emulsify lipophilic nutrients with an emulsifying composition consisting essentially of linoleic acid and vitamin E TPGS.

Claim Rejections – 35 U.S.C. §103

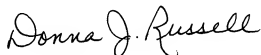
Claims 3, 4, 9 and 13-15 were also rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 5,824,638 to Burnside *et al* in view of U.S. 5,883,103 to Burnside *et al*, WO/29300 to Mishra *et al*, and Roy *et al* (FEBS Lett.). Roy teaches one of the benefits of vitamin E, while the teachings of Burnside and Mishra have been discussed above.

Applicants submit that both Burnside and Mishra provide disclosures that would indicate to one of skill in the art that compositions of the present invention would not be effective in the absence of a surfactant/detergent such as Tween® or Pluronic®. Rather than making the present invention obvious, these disclosures would discourage one of skill in the art from attempting the delivery of a therapeutic agent with a composition such as that provided by the inventors. The standard inquiry when evaluating the obviousness/non-obviousness of an invention is not whether it would be obvious to try an inventive composition, but whether it would be obvious that it would work. Applicants believe that the present invention, when viewed in light of the disclosures of Burnside and Mishra, would meet either test. It would not be obvious to

one of skill in the art to try the present combination in the absence of a detergent/surfactant, and it certainly would not be obvious that it would work. The inventors have discovered that it works very well, and provides compositions that provide lipophilic nutrients with greater efficiency than do previously disclosed compositions for the delivery of these therapeutic agents.

Should the examiner have questions or concerns related to this response, Applicants' representative may be reached by telephone at (615) 773-3583.

Respectfully submitted,

A handwritten signature in black ink that reads "Donna J. Russell". The script is cursive and fluid.

Donna J. Russell, Ph.D., J.D.
Attorney for Applicants
Registration No. 46,252
1492 Anthony Way
Mount Juliet, TN 37122
(615) 773-3583
Fax: (615) 758-9147

I hereby certify that this correspondence is being deposited with the United States Patent and Trademark Office's EFS system on April 12, 2008.

A handwritten signature in black ink that reads "Donna J. Russell". The script is cursive and fluid.